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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/671,106 | 09/28/2000 | Randal K. Buddington | 2343-104-27 | 8636 |

7590 06/10/2002

Patent Prosecution Services
Piper Marbury Rudnick & Wolfe LLP
1200 Nineteenth Street, N.W.
Washington, DC 20036-2412

[REDACTED] EXAMINER

EVANS, CHARESSEL

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 06/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/671,106 | BUDDINGTON ET AL. |
| | Examiner | Art Unit |
| | Charesse L. Evans | 1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 4-1-2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 8-14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 8-14 and 16-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Acknowledgement is made of the submission of applicant's RCE and Amendment filed on April 1, 2002.

Acknowledgement is made of the cancellation of claims 1, 4-7 and 15.

Claims 8-14 and 16-26 are pending in this Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-14 and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Green et al. (US 5,792,754). The claims are directed to a mixture of dietary fibers and methods of using the dietary fibers to treat, prevent and inhibit systemic infections in humans or vertebrates in humans and vertebrates who are at increased risk of developing systemic infections.

Green teaches a nutritional composition containing dietary fibers such as gum arabic, pectin, cellulose, hemicellulose, polysaccharides, oligosaccharides such as inulin and hydrolyzed inulin, resistant starch, lignin, levan or fructan, and carageenans (columns 2-3). The composition of the reference may be administered via tube feeding or oral consumption (column 2, lines 19-24). Furthermore, this composition, rich in dietary fiber, may be used to clear toxic compounds from the intestines by providing stool bulk and substrate for intestinal flora (column 1, lines 12-15).

Green discloses a fibrous composition that is basically the same as that recited in the claims, except that it does not teach inulin with an average degree of polymerization. It is the position of the examiner, however, that this parameter fails to impart a patentable characteristic. What is the criticality of utilizing inulin with this degree of polymerization?

The cited prior art reference teaches a fibrous nutritional composition that may be used as a complete food or a food supplement or clinical patients or infants. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). In this case, applicant's claims reads on ingesting a fiber material whereby the ingestion of that fiber material prevents or inhibits systemic infections of humans or vertebrates who are at an increased risk of systemic infections. What is it about applicant's claimed fiber that is different from the prior art?

Further, applicant has not shown any unexpected results obtained by utilizing inulin products with the claimed average degree of polymerization. As fiber is ingested and travels through the intestinal tract it, essentially, scrapes the niches, folds or walls of the intestinal tract thereby removing or displacing potentially toxic bacteria that reside on the surface of the intestinal walls. Because deposition of these potentially toxic pathogens on the intestinal walls tend to manifest as precursors for

intestinal disorders and diseases, it is important to regularly rid the intestinal tract of the potential pathogen. This is the function of fiber. It provides roughage and, as such travels through the digestive system virtually intact. One would have been motivated to modify the teachings of Green with the expectation that fiber hastens the amount of time it takes for feces to be eliminated, thereby minimizing the colon's exposure to naturally occurring carcinogens or pathogens – including byproducts of intestinal bacteria.

Conclusion

No claims are allowed at this time.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Marco et al. (US 5,856,313) discloses natural carob fiber and method of using same;
- Gilles et al. (US 6,248,375 B1) discloses diabetic nutritionals and method of using.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is

703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

cle
June 6, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
